

van Lengerich - Serial No. 09/782,320
AMENDMENT
Attorney Docket No. GMI-5238 (BVL-102A)

REMARKS

Claims 25-35, 37-43, 46-47, 50, 52-62, 64-71, 73, 75-76, 79, and 81-107 are pending herein. By this Amendment, non-rejected Claims 102 and 104 are canceled and their subject matter is incorporated into independent Claims 52 and 83, respectively. Allowed Claim 52 is also amended for clarity. Support for the claim amendments is found in the specification at, *inter alia*, pages 9-10 and in the original claims. No new matter is added by this Amendment.

Applicant thanks Examiner Webman for indicating that Claims 25, 27-31, 34-35, 37-40, 42, 46, 90-93, and 101 are allowed and that Claims 102-105 recite allowable subject matter.

Applicant respectfully notes that if Claim 90 is allowable then Claim 100, which depends from Claim 90 and simply recites the amount of encapsulant, should also be allowable and should not be withdrawn.

I. RESTRICTION/ELECTION OF SPECIES

Applicant respectfully notes that Claims 32-33 and 60 were previously examined and should not be withdrawn due to any restriction or elections of species requirement, as the election of species requirement directed to the rate-controlling agent (hydrophobic component) was withdrawn. Claim 76 has been examined and thus Claim 47, which recites the same subject matter but depends from allowed Claim 25, should not be withdrawn.

Applicant respectfully asserts that withdrawn Claims 26, 41, 53, 68, and 86-89 are generic to and readable on the elected species and should not be withdrawn. Also, once the generic claims are found allowable, Applicant respectfully notes that search and examination must continue as to a reasonable number of additional non-elected encapsulant and/or plasticized matrix material species.

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II. FORMAL MATTERS

Claim 95 [sic: 93] was rejected under 35 U.S.C. 112, first paragraph, as assertedly being non-enabled. This rejection is respectfully traversed.

The Examiner asserts that the specification does not disclose how to make a probiotic in liquid form. Applicants respectfully note that Claim 93, not Claim 95, is directed to a liquid encapsulant.

The specification states that the encapsulant may be in a solid form or a liquid form (specification at page 11, line 18-20). The encapsulant may be a nutraceutical component, such as a probiotic (specification at page 14, lines 9-26). Applicants attach hereto a printout from the website www.betterlife.com showing a "Blueberry Lactobacillus Probiotic, Liquid" for sale. Similarly, the attached printout from www.agmfoods.com shows "B.E. Wholegrain Liquid" as an original probiotic liquid. Thus, one of ordinary skill in the art would readily have been able to make a probiotic in liquid form without undue experimentation. Moreover, Applicants respectfully note that the Examiner has not provided any basis for his assertion regarding the lack of enablement for a liquid probiotic. As stated in MPEP 2164.04:

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention....As stated by the court, "it is incumbent upon the patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning...".

(Emphasis added). One of ordinary skill in the art would be able to make the claimed encapsulant in liquid form without undue experimentation. Thus, the requirements of 35 U.S.C. 112, first paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

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III. REJECTION UNDER 35 U.S.C. 103(a)

Claims 52, 54-59, 61-62, 64-67, 69-70, 73, 75-76, 79, 81-89, 90-93, and 95-97 were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 5,262,167 (Vegesna et al.) in view of U.S. Patent No. 5,716,615 (Cavaliere Vesely et al.), U.S. Patent No. 3,925,343 (Hampton et al.), and U.S. Patent No. 3,762,931 (Craig et al.). This rejection is respectfully traversed.

Vegesna et al. discloses a non-baked cholestyramine composition in which cholestyramine is in admixture with a carrier. The carrier is made up of a grain or flour, sugars, and starch binder, and may also contain an edible oil (Abstract). The composition comprises about 7 to about 20% by weight of one or more grain-based products (col. 2, lines 42-48). The composition of Vegesna et al. is a compressed agglomerate, not a matrix in which an encapsulant is substantially uniformly distributed. Vegesna et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; or (3) a lactobacilli encapsulant.

Cavaliere Vesely et al. does not overcome the deficiencies of Vegesna et al. Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus* and *Lactobacillus plantarum* or *Lactobacillus casei*. The composition may be useful in treating hypocholesterolemia (col. 1, lines 15-17). Like Vegesna et al., Cavaliere Vesely et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; or (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material. There is no teaching, suggestion, or motivation to combine Cavaliere Vesely et al. and Vegesna et al. The Examiner has not set forth any facts supporting the assertion that the addition of a lactobacillus agent to a non-baked cholestyramine composition would be expected to have a beneficial effect.

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Hampton et al. does not overcome the deficiencies of Vegesna et al. and Cavaliere Vesely et al. Hampton et al. discloses converting wheat gluten into agglomerates under conditions that do not denature the gluten so that the gluten can be dispersed in water to form a relatively stable dispersion (Abstract). Hampton et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient or (2) a *lactobacilli* encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material.

Craig et al. does not overcome the deficiencies of Vegesna et al., Cavaliere Vesely et al., and Hampton et al. Craig et al. discloses a process for making macaroni (pasta) products including mixing and extruding a paste (Abstract). Craig et al. states that flour obtained from durum wheat is needed to make macaroni products under high pressure. See col. 1, lines. 13-25 and 31-39. There is no teaching or suggestion to substitute the durum wheat of Craig et al. for the pregelatinized starch binder in Vegesna et al. In fact, there is no reason why one of ordinary skill in the art would seek to use the durum wheat of a smooth, hard, glassy pasta or macaroni product as obtained in Craig et al. for the coarse, granola-like, chewable granules disclosed in Vegesna et al.

None of the cited references teaches or suggests the combination of: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; and (3) a *lactobacilli* encapsulant.

Nevertheless to reduce the issues for prosecution, non-rejected Claims 102 and 104 are canceled and their subject matter is incorporated into independent Claims 52 and 83, respectively. Reconsideration and withdrawal of the rejection are respectfully requested.

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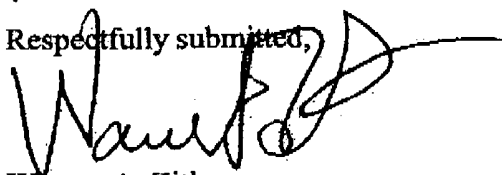
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IV. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket No. BVL-102A).

Respectfully submitted,



Warren A. Zitlau

Registration No. 39,085

Barry I. Hollander

Registration No. 28,566

Hollander Law Firm, P.L.C.
Suite 305, 10300 Eaton Place
Fairfax, VA 22030
Tel: (703) 383-4800
Fax: (703) 383-4804

May 26, 2004

Enclosures:

"Blueberry Lactobacillus Probiotic, Liquid" (www.betterlife.com)

"B.E. Wholegrain Liquid" (www.agmfoods.com)

B.E. Wholegrain Liquid

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**B.E. Wholegrain Liquid**

1.25L

Manufactured in Australia

Nature's Fast Food**Dairy Free, Non GMO, No Sugar Added**

- Refreshing
- Effervescent
- Original probiotic liquid
- Naturally fermented
- Friendly bacteria
- All natural, organic ingredients
- Traditional good health liquid

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This is the original probiotic liquid produced by AGM Foods Pty. Ltd. It is a refreshing, effervescent liquid, an active source of friendly lactobacillus bacteria, a natural source of vitamins, minerals, amino acids and enzymes. B.E. Wholegrain Liquid is a high quality probiotic liquid, produced through an entirely natural, organic fermentation process. B.E. Wholegrain Liquid is formulated to achieve high, active levels of probiotic bacteria sustained in a ready, liquid medium immediately available for use within the digestive system.

It has been well-documented that a good source of probiotic bacteria in the diet is helpful and that they are a natural part of the food chain. Many modern diets include caffeine, sugar, simple carbohydrates, preservatives and overly processed foods. All these factors can lead to reduced levels of probiotic bacteria in the intestinal system, providing an environment for putrefactive bacteria to dominate. Including B.E. Wholegrain Liquid in the diet regularly may help replenish the supply of probiotic bacteria and replace those lost through normal body functioning.

Because the B.E. Wholegrain Liquid is an active source of lactobacillus bacteria, the liquid is self-carbonating, we recommend refrigeration of the product after opening. Gently shake the bottle and untwist the cap slowly to release gas. There will be a little sediment in the bottom of the bottle that is necessary for food for the bacteria.

Dilute with water, freshly squeezed juices, add to recipes, use in smoothies and salad dressings, or drink neat.

Purchase this product >>**INGREDIENTS:**

Malt, Whole Organic: (Oats, Maize, BD Rice, Alfalfa Seed, Pearl Barley, Linseed, Mung Beans, Rye Grain, Wheat, Millet), Buckwheat, Filtered Water added, PLUS Lactobacillus acidophilus, Lactobacillus delbreuckii,

TYPICAL ANALYSIS		
NUTRIENT	PER 100mL SERVE	PER 50mL SERVE
Energy	53.7 kJ	26.8 kJ

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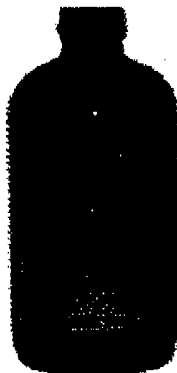
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**Blueberry Lactobacillus
Probiotic, Liquid****Nature's Life****NL540****16 Ounces****~~\$8.95~~****\$6.71****Long Description**

Nature's Life - Blueberry Lactobacillus Acidophilus (Liquid)

- Billions of "Friendly Bacteria"
- Thick & creamy with natural blueberry flavor
- Live Probiotic Organisms
- Soy Based / Milk-Free
- NOT Filtered or Centrifuged
- Refrigeration Required

Directions: Take 1 tablespoons(0.5 fl oz or 15ml) as desired.**Ingredients:** 1 Tablespoons(15ml) supplies: Calories 5, Total fat 0g, Total Carbohydrates 1g, Sugars <1g, Protein <1g. **VEGETARIAN FORMULA.****Other Ingredients:** Purified water, non-GMO soy protein isolate, pure crystalline fructose, fructooligosaccharides, natural blueberry flavor, live lactobacillus acidophilus culture(L. acidophilus, L. bulgaricus, L. thermophilus, L. rhamnosus, bifidobacterium lactis, bifidum and infantis). DOES NOT contain yeast, milk or other dairy products, corn, wheat gluten, rye, soy, rice, starch, wax, di-calcium phosphate, preservatives, flavoring, coloring or animal by-products.**Recommend To Someone You Know**

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